

8EHQ-11-18404

337186

RECEIVED  
OPPT CBIC

PUBLIC COPY

2011 AUG -2 AM 10:44

August 1, 2011

Via Federal Express

Document Processing Center (Mail Code 7407M)  
Room 6428  
Attention: 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
1201 Constitution Ave., NW  
Washington, DC 20004



Dear 8(e) Coordinator:

2-[(substituted-2-carbobicyclyl)substituted]-N-(alkoxy-1,1-dialkyl)alkylamide

This letter is to inform you of the results of a developmental toxicity study in rats with the above referenced R&D test substance. To the best of our knowledge, this substance is not on the TSCA inventory.

Groups of 8 time-mated Crl:CD®(SD) rats were administered formulations of the test substance in 0.5% methylcellulose with 0.1% Tween 80 by once daily gavage on gestation days (GD) 6-20 at daily dose levels of 0 or 1000 mg/kg/day. The dose volume was 10 ml/kg for all groups. The control group rats were dosed with the vehicle only. During the in-life portion of the study, maternal clinical observations, body weights, and food consumption data were collected. On GD 21, all dams were euthanized and a gross external and visceral examination was performed. The uterus of each pregnant female was removed and the uterine contents were examined and described; all fetuses were removed and individually identified, weighed, sexed, and examined for external alterations. Maternal toxicity was observed at 1000 mg/kg/day and consisted of statistically significant, test substance-related reductions in body weight and food consumption parameters throughout the study. One animal in the treated group was euthanized prior to scheduled sacrifice on gestation day 18 due to marked body weight loss, reduced food consumption and clinical signs including high posture, red urine, and stained black skin/fur. No other early deaths occurred on this study. There were no remarkable clinical signs of toxicity observed for the control or treated group. Adverse developmental toxicity was observed at 1000 mg/kg/day and included a markedly increased incidence of dams with totally resorbed litters (6/7 litters). As a result, evaluation and interpretation of mean fetal weight, litter size, and fetal alterations was not possible under the conditions of this study.

Sincerely,



Company Sanitized